

III. Remarks

A. Status of the Application

Claims 12-21 and 31-40 are pending. Claims 12-21 and 31-39 were previously pending. New claim 40 is added by the present paper. No claims are canceled by the present paper. Applicants request reconsideration of the application in light of the above amendments and the following remarks.

B. Objections to the Drawings and Rejections under 35 U.S.C. §112, First Paragraph

The drawings are objected to under 37 CFR 1.83(a). Specifically, the drawings are objected to as not showing every feature of the invention specified in the claims. The Office Action states that “the ‘implant’ inserted between the first and second vertebrae in combination with the first and second insertion members inserted into the sidewall that are connected by an elongate member or a connecting member that spans the distance between the vertebrae must be shown.”

Claims 14-16 stand rejected under 35 U.S.C. §112, first paragraph. Specifically, the Office Action asserts that the specification does not enable one skilled in the art to use the invention commensurate with the scope of these claims. The Office Action states that “the specification, while being enabling for preparation of the vertebrae by possibly forming bores in the sidewall that receives the insertion members or screws, does not reasonably provide enablement for laterally forming slots in the first and second vertebrae.”

Claims 31-39 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The Office Action states that “[t]he disclosure does not describe the method of correcting spondylolisthesis as including the use of lateral screws and an elongate member or rod in combination with insertion of an implant between the vertebrae.” Further, with respect to claim 37, the Office Action states that “the disclosure

describes the insertion of the apparatus described above, but fails to describe the removal of the apparatus.”

The objection to the drawings and the §112 rejections of claims 14-16 and 31-39 are all related to the disclosure of a method that includes both correcting spondylolisthesis from a lateral approach and inserting an implant between the vertebrae from a lateral approach. Generally, Applicants would direct the Examiner to the “Lateral Correction” portion of the application at paragraphs [0072]-[0119] (as numbered in the published application) and Figs. 1-13 for this disclosure. More specifically, paragraphs [0078]-[0083] along with Figs. 3a and 3b disclose a method of correcting spondylolisthesis from a lateral approach using a pair of bone screws 30, 32 and a rod 34. Subsequently in the “Lateral Correction” portion, paragraphs [0100] and [0115] along with Figs. 7 and 19 disclose preparation of “the partially corrected upper and lower vertebrae” and insertion of a prosthetic joint between the partially corrected vertebrae. Similarly, paragraphs [0101], [0102], [0116], and [0117] along with Figs. 8 and 10 disclose preparation of “fully corrected” vertebrae and insertion of a prosthetic joint between the fully corrected vertebrae. It is clear that the disclosed method of correcting spondylolisthesis is utilized to partially or fully correct the spondylosed vertebrae and that the partially or fully corrected vertebrae are then prepared to receive a prosthetic device.

The Office Action appears to be concerned with using the rod and screws for reducing the spondylolisthesis in combination with the prosthetic joint. However, it is clear from the disclosure discussed above that the rod and screws are utilized for adjusting the position of the vertebrae relative to one another and that the vertebrae are prepared to receive the prosthetic device after partial or full correction of the spondylolisthesis. The office action asserts that “[i]f the lateral slots are formed for the implant, there is no safe area in the lateral sidewall then to receive the bone screws for the elongate rod or vice versa.” However, as shown in Figs. 3a, 3b, 7, 8, 10, and 11, the openings 104, 106 in the vertebrae for receiving the keels of the prosthetic device are adjacent the disc space, while the bone screws 30, 32 are inserted into the vertebral bodies at a position spaced from both the disc space and the portion of the vertebrae where the openings for receiving the keels are formed. Accordingly, as illustrated, the openings for the

implant and the insertion points for the bone screws do not interfere with one another as suggested.

The Office Action also appears to be concerned with the potential for the rod and screws utilized in correcting the spondylolisthesis to block the lateral access to the vertebrae for preparing the vertebrae to receive the implant and/or insertion of the implant. For example, the Office Action questions, "how is it possible to form lateral slots if the sidewalls of the vertebrae receive the screws for the attachment of the elongate member, i.e. rod of which is attached to the lateral side spanning the vertebrae?" However, it is clear to one skilled in the art from the disclosure that the rod utilized for moving the vertebrae relative to one another is removed prior to insertion of the prosthetic joint. In that regard, the rod and screws of the present application are utilized for moving the vertebrae to correct the spondylolisthesis, not for stabilizing the vertebrae after correction (as disclosed in the cited references). Accordingly, the rod and screws of the present application do not need to remain secured to the vertebrae after moving the vertebrae. As the Examiner recognizes with his question, it is unclear how one would laterally prepare the vertebrae and insert the prosthetic device from a lateral approach without removing the rod. Further, the application explicitly or implicitly discloses that the rod is removed. For example, Figs. 7, 8, 10, and 11 and the related description discussing the preparation of the partially or fully corrected vertebrae for receiving the prosthetic device do not show the rod and screws, indicating that they have been removed after the full or partial correction of the spondylolisthesis. Further, in some embodiments the present application utilizes motion-preserving prosthetic devices whose function would be destroyed by maintaining the rigid connection between the vertebrae established by the rod. Accordingly, it is apparent to one skilled in the art from the drawings and written description of the present application that the rod would be removed prior to preparation of the vertebrae for receiving the prosthetic device.

Thus, Applicants request that the objections to the drawings and the rejections under 35 U.S.C. §112, first paragraph of claims 14-16 and 31-39 be withdrawn.

C. Rejections under 35 U.S.C. §102

Claims 12, 13, 17, 21, 31-35, and 38 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,108,395 to Laurain (“the Laurain patent”). The PTO provides in MPEP § 2131 that

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (emphasis added)

Therefore, to sustain the rejection of claims 12, 13, 17, 21, 31-35, and 38 the Laurain patent must disclose each and every element in as complete detail as recited in the claims.

With respect to independent claims 12 and 31, however, the Laurain patent at least fails to disclose “applying a rotating force to the connecting member from a substantially lateral approach to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween.” First, the Laurain patent explicitly notes that “[t]he subject of the present invention is an implant for **anterior** dorsolumbar spinal osteosynthesis,” “the object of the invention is therefore to provide an implant having the advantages of these two categories of prior devices without having their disadvantages so as to carry out an **anterior** reconstruction of the dorso-lumbar spine,” and “[t]he implant 1 [is] intended to be fitted **anteriorly** onto the vertebral bodies.” Col. 1, ll. 6-9, Col. 2, ll. 31-36, and Col. 4, ll.13-14 (emphasis added).

Second, the vertebrae in the Laurain patent are moved by distracting forceps, not by rotating the plate 6. Specifically, the Laurain patent states that “[t]he surgeon then fits the distracting forceps (FIG. 7), the tips 21a of which fit into the notches 23 against which they bear, so as to permit distraction and to correct the kyphosis.” Col. 6, ll. 65-68. With respect to the plate 6 and clamps, the Laurain patent notes that “means for adjusting the angle of the plate 6 relative to the clamps 2 and for locking in rotation (complementary serrations 18 and 19) enable the implant to be fitted with a maximum amount of flexibility, and likewise **adaptability to the anatomical conditions of the spinal segment in question**.” Col. 7, ll. 47-52. In other words,

the clamps and plate are adjusted to the orientation of the vertebrae. The plate is simply not rotated to adjust the orientation of the vertebrae as required by claims 12 and 31.

For at least these reasons, the Laurain patent fails to disclose each of the recited elements of independent claims 12 and 31. Claims 13, 17, 21, 32-35, and 38 depend from and further limit claims 12 and 31. Thus, for at least the same reasons the Laurain patent fails to disclose each of the recited elements of these claims as well. Further, with respect to claim 21, the Laurain patent does not disclose rotating the plate 6 with a rotatable wrench as required. In that regard, the Office Action notes that “the surgeon uses a wrench to rotate the screws.” But claim 21 requires the connecting member, not the insertion members. Accordingly, for this additional reason the Laurain patent fails to disclose all of the recited elements of claim 21.

Thus, Applicants request that the §102 rejection of claims 12, 13, 17, 21, 31-35, and 38 be withdrawn.

D. Rejections under 35 U.S.C. §103

Claim 36 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent. As shown above, however, the Laurain patent fails to disclose each of the elements of independent claim 31 from which claim 36 depends from and further limits. Accordingly, for at least the same reasons the Laurain patent fails to disclose or suggest all of the elements of claim 36. Thus, Applicants request that the §103 rejection of claim 36 over the Laurain patent be withdrawn.

Claims 18 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent in view of U.S. Patent No. 6,030,389 to Wagner et al. (“the Wagner patent”). As shown above, the Laurain patent fails to disclose each of the elements of independent claim 12, from which claims 18 and 19 depend from and further limit. The Wagner patent does not affect this deficiency. Accordingly, even when combined the Laurain and Wagner patents fail to disclose all of the recited elements of claims 18 and 19. Thus, Applicants request that the §103 rejection of claims 18 and 19 over the Laurain and Wagner patents be withdrawn.

Claim 20 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent in view of U.S. Patent No. 5,306,275 to Bryan (“the Bryan patent”). As shown above, the

Laurain patent fails to disclose each of the elements of independent claim 12, from which claim 20 depends from and further limits. The Bryan patent does not affect this deficiency.

Accordingly, even when combined the Laurain and Bryan patents fail to disclose all of the recited elements of claim 20. Thus, Applicants request that the §103 rejection of claim 20 over the Laurain and Bryan patents be withdrawn.

Claim 37 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent in view of U.S. Patent No. 5,382,248 to Jacobson et al. (“the Jacobson patent”) and U.S. Patent No. 6,749,612 to Conchy et al. (“the Conchy patent”). As shown above, the Laurain patent fails to disclose each of the elements of independent claim 31, from which claim 37 depends from and further limits. The Jacobson and Conchy patents do not affect this deficiency. Accordingly, even when combined the Laurain, Jacobson, and Conchy patents fail to disclose all of the recited elements of claims 37. Thus, Applicants request that the §103 rejection of claim 37 over the Laurain, Jacobson, and Conchy patents be withdrawn.

Claims 12, 13, 17, 20, 21, and 31-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,964,665 to Thomas et al. (“the Thomas patent”) in view of the Laurain patent.

The PTO provides in MPEP §2131 that

“The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.”

The Examiner clearly cannot, using the Thomas and Kapp patents, establish a prima facie case of obviousness in connection to claims 12, 13, 17, 20, 21, and 31-35 for at least the following reasons.

35 U.S.C. §103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .”
(emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

However, even when combined the Thomas and Laurain patents fail to disclose all of the recited limitations of independent claims 12 and 31. In that regard, the Office Action asserts that the Thomas patent discloses the recited limitations of these claims, except that the Thomas patent “fails to disclose that the spinal disc would need to be removed or to place an implant between the vertebrae.” Applicants respectfully disagree. First, Applicants disagree with the Office Action’s assertion that one skilled in the art would consider the pedicle of a vertebrae a “sidewall” of the vertebrae. Regardless, Applicants have amended claim 12 to clarify that the insertion members are inserted into a lateral sidewall of the vertebrae. Thus, even under the Office Action’s interpretation, the Thomas patent fails to disclose this limitation of claim 12.

Second, the Thomas patent also fails to disclose “applying a rotating force to the connecting member from a substantially lateral approach to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween” as recited in independent claims 12 and 31. The Thomas patent simply does not disclose applying a rotating force to rods 50 to rotate the vertebrae relative to one another as asserted in the Office Action. Rather, the Thomas patent explicitly states that “[t]he alignment rods 10 are [] used to manipulate and align the vertebral body 52 to the desired angle and position ... the surgeon would ... pull or push the vertebral body to correct spondylolisthesis ... **Once the surgeon has manipulated the vertebral bodies into the proper, or desired, alignment,** the fixation hardware is slipped down the shaft of the alignment rod 10.” Col. 6, Lines 37-67 (emphasis added). Applicants would point out that the alignment rods 10 that are utilized to adjust the position of the vertebral bodies do **not** extend between vertebrae as required of the connecting member of claims 12 and 31, but rather each alignment rod 10 is connected to a single vertebrae. The rods 50 are then used to secure the vertebrae in position after positioning of the vertebrae with the alignment rods.

In addition, the Thomas patent fails to disclose applying a rotating force from a substantially lateral approach as required. Consistent with the drawings of the Thomas patent and the corresponding description explaining that a surgeon would “pull or push the vertebral

body to correct spondylolisthesis,” it is clear that the Thomas patent discloses only a substantially posterior approach to correcting spondylolisthesis. The Thomas patent clearly does not disclose the substantially lateral approach as required. The Office Action asserts that there must be some overlap between the “substantially lateral” approach recited in the claims and the “substantially posterior” approach disclosed by the Thomas patent. Applicants respectfully disagree. One skilled in the art certainly would not consider a substantially posterior approach as being a substantially lateral approach. While the term “substantially” as utilized in the claims does provide some variance to the lateral approach beyond a direct lateral approach, it still requires the approach to be substantially or mostly from the lateral direction. Similarly, a substantially posterior approach must be substantially or mostly from the posterior direction. Accordingly, one skilled in the art simply would not consider a substantially posterior approach to be a substantially lateral approach. Thus, the approach of the Thomas patent that is substantially posterior necessarily cannot be considered to disclose the substantially lateral approach recited in the claims.

Further, as noted above with respect to the §102 rejections, the Laurain patent fails to disclose the recited limitations of claims 12 and 31 as well.

Accordingly, for at least these reasons even when combined the Thomas and Laurain patents fail to disclose all of the recited elements of independent claims 12 and 31. Claims 13, 17, 20, 21, and 32-35 depend from and further limit claims 12 and 31. Thus, for at least these reasons Applicants request that the §103 rejection of claims 12, 13, 17, 20, 21, and 31-35 over the Thomas and Laurain patents be withdrawn.

Claims 14-16 and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Thomas and Laurain patents as applied to claims 13 and 31 in further view of U.S. Patent No. 5,314,477 to Marnay (“the Marnay patent”). As discussed above, even when combined the Thomas and Laurain patents fail to disclose all of the recited elements of claims 12 and 31 from which claims 14-16 and 39 depend. The Marnay patent does not affect this deficiency. Accordingly, for at least the same reasons the Thomas, Laurain, and Marnay patents fail to disclose all of the limitations of claims 14-16 and 39. Therefore, Applicants request that the

§103 rejection of claims 14-16 and 39 over the Thomas, Laurain, and Marnay patents be withdrawn.

E. New Claim

New claim 40 has been added and recites a combination of limitations not disclosed by the cited references. In particular, new independent claim 40 recites:

A method of correcting spondylolisthesis comprising:
removing an intervertebral disc between a first vertebra and a second vertebra in a spondylosed relationship to form an intervertebral space;
inserting a first bone screw into a lateral sidewall of the first vertebra via a lateral approach;
inserting a second bone screw into a lateral sidewall of the second vertebra via a lateral approach;
fixedly engaging a rod with the first and second bone screws such that the rod extends between the first and second vertebrae;
rotating the rod from a lateral approach to adjust the positions of the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween;
disengaging the rod from the first and second bone screws;
creating a first elongated recess in the first vertebrae adjacent the intervertebral space via a lateral approach;
creating a second elongated recess in the second vertebrae adjacent the intervertebral space via a lateral approach; and
inserting a motion-preserving implant into the intervertebral space such that a first projection of a first component of the implant engages the first recess and a second projection of a second component of the implant engages the second recess, the first and second components configured to articulate with one another.

IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all pending claims are in condition for allowance. Accordingly, Applicants request an indication of allowance of the pending claims. If an interview would expedite prosecution in any way, the Examiner is invited to contact the Applicants' undersigned representative.

Respectfully submitted,



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